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09/753,143	01/02/2001	Nathan Ellis	63475/263	1780

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AMSTER, ROTHSTEIN & EBENSTEIN
90 Park Avenue
New York, NY 10016

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,143

Applicant(s)

ELLIS ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 14-17, 19, 20 and 86-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14-17, 19, 20 and 86-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a Final rejection (mailed on September 26, 2003), Applicants filed an after-final response and amendment received on November 20, 2003. Said amendment was not entered (see Advisory Action mailed December 24, 2003) before the filing of a request for continued examination (RCE) by Applicants (January 13, 2004). Said amendment has now amended Claims 1 and 86-93. Thus, Claims 11, 12, 14-17, 19-20, and 86-93 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/175,828 and 08/559,303 filed on October 20, 1998 and November 15, 1995.

Withdrawn - Objections to the Specification

3. Previous rejection of the specification for containing new matter as introduced by the amendment filed July 17, 2003 is withdrawn by virtue of Applicants' removal of said new matter.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

4. Previous rejection of Claims 86, 89, and 91 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicants' explanation using the footnotes, which as noted above, are relatively unreadable due to small font size. However, footnote "g" clearly refers to

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139(ViKre) due to the inclusion of the position in the definition of the footnote; and footnote “i” clearly refers to all of the 6 bp del/7 bp ins listed in the table.

Maintained - Claim Rejections - 35 U.S.C. § 112

5. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “*BLM* gene” is maintained; the rejection of Claims 86-93 is herein withdrawn. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that the additional limitation of a chromosomal location obviates the rejection; the Examiner disagrees. The location in the claims is over 250 kb as described in the specification, and no limitation on the number and/or kind of mutations to the wild type *BLM* gene is found in the claims. Thus, virtually any portion of the 250 lb section of chromosome can be envisioned. It is precisely Applicants’ quote of the definition of a mutated *BLM* gene from the specification (see page 8, lines 1-6) that is limitless in the number of insertions, deletions, etc. resulting in the unclear breadth of the pending claims.

As previously noted, “although the instant specification focuses on identifying point or limited mutations in a subject’s *BLM* gene, no requirement for maintaining any particular *BLM* gene character is required; no requirement of being a DNA helicase is required.”

6. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, first paragraph, written description, is maintained; previous rejection of Claims 86-93 is withdrawn herein. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that the specification teaches a link between a mutated *BLM* gene and Bloom’s syndrome; the Examiner does not disagree. However, not all mutations of the *BLM* gene result

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in Bloom's syndrome since some would not affect the DNA helicase nature of the encoded protein. And, more to the point, the term "mutated BLM gene" has been defined so broadly in the specification that the BLM-nature of the gene in the method is suspect. As previously noted, "there are no particular method steps requiring the use of a nucleic acid encoding SEQ ID NO:78. Thus, the materials used to practice the method are not adequately described. As previously noted,

"a mutated BLM gene is described as SEQ ID NO:72 with any number of deletions, insertions, point mutations, and/or rearrangements mutations (see page 8). Thus unlimited mutation broadens the scope of a "mutated BLM gene" to be virtually *any* structure. In the instant specification, a single example of a human Bloom's syndrome-linked gene is described. However, in view of this broad interpretation of a "mutated BLM gene" defined in the specification, no common structure of the genus of mutated BLM genes can be recognized."

As previously noted, "the Examiner suggests adding method steps to the instant claims that utilize SEQ ID NO:72 in some hybridization step. Such claims would limit the scope of a "mutated BLM gene" by virtue of the hybridization language." In the case of detecting the mutated gene via protein means (Claim 17), alternate claim language would have to be sought and supported in the specification as originally filed.

7. Previous rejection of Claims 11, 12, 14-17, and 19-20 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained; rejection of Claims 86-93 is withdrawn herein. Applicants' arguments are identical to those for the rejection under written description above. Said arguments have been addressed above.

As noted above and previously,

"the definition of mutated BLM gene is so broad that numerous species of the genus would not be recognized by common techniques in the art. As such, these structurally dissimilar, mutated BLM genes would require undue experimentation for their detection. ...

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The specification describes examples of using the disclosed BLM gene to identify BLM genes in other subjects. The subject's BLM gene can then be compared to the wild type, or normal, BLM gene. No working examples are described wherein the mutated BLM gene is significantly different in structure from the disclosed BLM gene. No guidance for surmounting such problems is offered. While the relative skill of those in the prior art is high, the predictability of identifying mutated BLM genes is strictly linked to the ability to find the mutant gene by its structural relationship to that which is disclosed in the instant specification. The predictability of finding highly dissimilar sequences is very low. Thus, the instant claims are not enabled to the full extent of their scope."

NEW ISSUES

Objections to the Specification

8. The specification is objected to for a typographical error. Each occurrence of the author's name "Guappay" is a typographical error; the correct spelling is ---Guapay---. For example, see pages 13-14. Correction is required.
9. The specification is objected to for lacking clarity in Table 1. The footnote of "g" in ID 139(ViKre) is confusing because "g" describes an insertion and 139(ViKre) is described as having a point mutation. Also, the footnote letters on 15(MaRo) through 92(VaBi) are unreadable as are other characters in the table, due to the small font of the letters; the Examiner suggests resubmitting the Table in an increased font size.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11, 12, 14-17, 19-20, and 86-93 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. The language of Claim 11 is confusing because in the preamble, the subject is not required to be a human subject yet the mutated gene must be found in a section of human chromosome; clarification is required.

Summary of Pending Issues

11. The following is a summary of the issues pending in the instant application:
- a) The specification is objected to for a typographical error.
 - b) The specification is objected to for lacking clarity in Table 1.
 - c) Claims 11, 12, 14-17, and 19-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “*BLM* gene”.
 - d) Claims 11, 12, 14-17, 19-20, and 86-93 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the language of Claim 11 in the preamble.
 - e) Claims 11, 12, 14-17, and 19-20 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
 - f) Claims 11, 12, 14-17, and 19-20 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Examiner Comments

12. The Examiner suggests claim language that uses a nucleic acid sequence encoding SEQ ID NO:78 in (a) a hybridizing step followed by (b) a sequencing step to identify mutations in a subject's *BLM* gene. Such a method would detect not only mutated *BLM* genes but also unmutated *BLM* genes (subjects free of Bloom's syndrome). Moreover, such a claim could be limited to identifying particular mutations such as in Claim 86.

Conclusion

13. Claims 11, 12, 14-17, 19-20, and 86-93 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
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March 29, 2004